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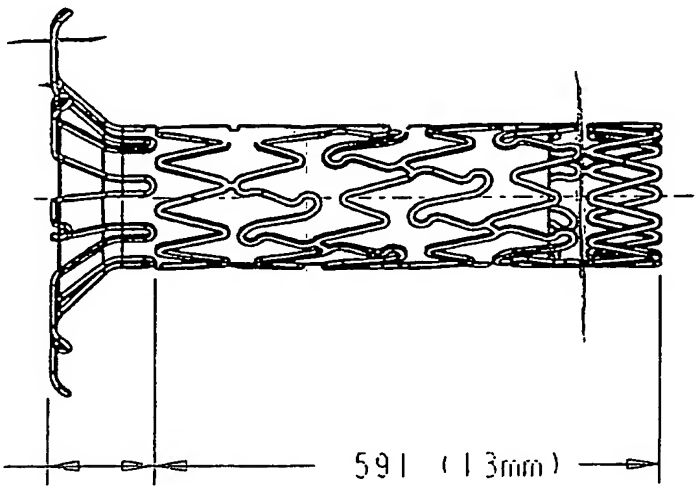
(54) Title: FLARED OSTIAL ENDOPROSTHESIS AND DELIVERY SYSTEM




(57) Abstract: An intraluminal endoprosthesis having a conically shaped first end and a tubular shaped balloon-expandable stent for a main body is disclosed. The conically shaped first end may form a flare to the main body and is particularly well suited for in ostium use. The first end is preferably self-expanding and the main body is preferably balloon-expandable. Also disclosed is a delivery device for delivering intraluminal ostial endoprosthetic devices, especially those disclosed herein, to a site for deployment. The delivery device may comprise an over-the-wire system or may comprise a rapid-exchange shuttle system. The self-expanding portion of the endoprosthesis is encapsulated in a sheath or other restraining apparatus on the delivery device. The balloon-expandable stent portion of the endoprosthesis is crimped onto a balloon delivery device. The delivery system and endoprosthesis of the present invention allow the endoprosthesis to be partially expanded and relocated if it is determined that it is not located in the proper location. To aid in positioning, the delivery device may comprise marker bands.

# Flared Ostial Endoprosthesis and Delivery System

## BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to intraluminal endoprosthetic devices. In particular, the present invention relates to ostial intraluminal endoprosthetic devices and delivery systems and methods for deploying them.

2. Description of Related Art

Stents are prosthetic devices that are implanted in the lumen of a vessel inside the body to provide support for the wall of the vessel. Typically, stents are implanted within a vessel system to reinforce vessels that are partially occluded, collapsing, weakened, or abnormally dilated. In some cases, stents may be used to address ostial lesions in renal, subclavian, carotid, LCA, RCA, and SVG coronary bypass graft anastomosis sites, as well as in other locations. More generally, stents can be used inside any physiological conduit or duct, including arteries, veins, bile ducts, the urinary tract, alimentary tracts, the tracheobronchial tree, a cerebral aqueduct or the genitourinary system, for example. Stents may be used in both humans and animals.

There are typically two types of stents: self-expanding stents and balloon-expandable stents. Self-expanding stents automatically expand once they are released and assume a deployed, expanded state. A balloon-expandable stent is expanded using an inflatable balloon catheter or other balloon delivery device. The balloon is inflated to plastically deform the stent. Balloon-expandable stents may be implanted by mounting the stent in an unexpanded or crimped state on a balloon segment of a catheter. The catheter, after having the crimped stent placed thereon, is inserted through a puncture in a vessel wall and moved through the vessel until it is positioned in a portion of the vessel that is in need of repair. The stent is then expanded by inflating the balloon catheter against the inside wall of the vessel. The stent is plastically deformed by the inflation of the balloon so that its diameter increases and remains at an increased state. In some situations, the vessel that the stent is implanted into may be dilated by the stent itself when the stent is expanded.

Balloon-expandable stents are more easily and more accurately positioned because they can be expanded slowly, uniformly, and without undue movement axially during placement. A balloon-expandable stent may be moved within a vessel even after it has started to expand. In contrast, self expanding stents are more difficult to position and more difficult to move once they have started to expand. Self expanding stents, while more difficult to align and accurate place within a vessel do have some advantages, particularly when addressing ostial lesions in vessels.

Self-expanding stent exert continual outward radial force and form a "pre-determined" shape or diameter. This is particularly useful when trying to address ostial lessions.

## SUMMARY OF THE PRESENT INVENTION

The present invention is directed to intraluminal endoprosthetic devices having a flared or conical end region and delivery systems for positioning them within lumens of vessels. In one embodiment, the present invention comprises a balloon-expandable stent coupled with a self-expanding flared region. When the endoprosthesis is deployed, its self-expanding region forms a conical or a flare shape. The self-expanding region is coupled to the balloon-expandable stent with an encapsulating material or membrane. In some embodiments, the encapsulating material covers a portion of both the self-expanding region and the balloon-expandable stent or covers and/or encapsulates both entirely.

The present invention also provides for a delivery system for flared intraluminal ostial endoprosthetic devices. In one embodiment, an intraluminal ostial endoprosthesis is delivered to a site with a delivery apparatus having a distal region. A balloon delivery device is mounted over the distal region of the delivery apparatus so as to encapsulate it, or at least a portion of it. A balloon-expandable region, which is comprised of a balloon-expandable stent, is crimped onto the balloon delivery device. A sheath or retaining device, such as a ring, is mounted over a self-expanding region of the endoprosthesis. The delivery apparatus of the present invention may traverse a guidewire, may be delivered to the site of interest via a rapid-exchange shuttle, or may be an "over-the-wire" type device. In some embodiments, it is desirable to include marker bands on the distal region of the delivery apparatus so the location and/or orientation of the endoprosthesis, which is mounted thereon, may be ascertained during deployment. In one embodiment, the delivery device has three marker bands, a distal marker band, a proximal marker band, and a middle marker band. The distal marker band is the most distal of the three and the proximal is the most proximate of the three.

Once the endoprosthesis is delivered to the general region where it is to be implanted, the balloon device is partially inflated. Often it is necessary to use radiological or other techniques for determining the precise location of the endoprosthesis. If it is not located at a proper location, even in a partially inflated state, it may be repositioned. After it is confirmed that it is in the proper location, the balloon is completely inflated. This inflation plastically deforms the balloon-expandable portion of the endoprosthesis. In one embodiment, as the balloon expands, the sheath begins to pull back from the self-expanding region and the self expanding region deploys to its predetermined size. The delivery balloon is then deflated and the delivery apparatus is removed from the vessel.

In another embodiment, the balloon is inflated and then a capture sheath, ring, or other sutiable restraining apparatus is removed from the endoprosthesis's self-expanding regions. The restraining apparatus may be removed at any time during deployment. In one embodiment, it is removed after the balloon is fully inflated. In other embodiments, it is removed from the self-expanding region before the balloon is inflated or after the balloon is only partially inflated.

## BRIEF DESCRIPTION OF THE DRAWINGS

The file of this provisional patent application contains at least one drawing executed in color.

Figure 1 depicts an endoprosthesis according to the present invention in an "as deployed" view, when used to address a renal arterial indication.

Figures 2a-2f depict exemplary flared sections of the endoprosthesis of the present invention.

Figures 3a-3j depict exemplary web-mesh patterns for the flared portion of the endoprothesis of the present invention.

Figures 4a-4b illustrate the web-mesh pattern of a support structure for one embodiment of the present invention.

Figure 5 illustrates an endoprosthesis according to the present invention after it has been mounted on a delivery device according to the present invention.

Figures 6-12 illustrate the use of the delivery device in deploying an ostial intrluminal endoprosthesis.

Figures 13-18 illustrate the endoprosthesis of the present invention after it has been deployed at an ostium.

Figures 19-118 illustrate various aspects of various embodiments of the endoprosthetic devices, the delivery devices, and the methods of deploying the endoprosthetic devices of the present invention.

## DETAILED DESCRIPTION OF THE PRESENT INVENTION

The present invention is directed to flared ostial endoprosthetic devices for intraluminal use. As is shown in Figure 1, which depicts an embodiment of the endoprosthesis according to the present invention when it is deployed in a renal artery **90** branching from an aorta **95**, the endoprosthesis may have a balloon-expandable stent region **100** and a self-expanding end-region **200**, wherein when the endoprosthesis is deployed, the self-expanding region assumes a flared state. The balloon-expandable stent region preferably has a design that allows for a high stent-to-vessel ratio. In some embodiments, the balloon-expandable stent region **100** will comprise a plurality of helical segments and preferably has a geometry that allows the balloon-expandable stent region to be crimped onto a delivery device. Numerous designs are known in the art and may be used for the balloon expanding region. For example co-pending applications 10/014,705 to Addonizio et al (December 11, 2001) and provisional application 60/267,778 to Pazienza et al (Feb. 2, 2001) disclose designs well-suited for use in the balloon-expandable region. Both provide for stents having high stent to vessel ratios and both employ a plurality of helical

segments that expand circumferentially when the stent is expanded by a balloon device. Other balloon-expandable stent designs, which are well-known in the art, may also be used.

In some embodiments, it may be desirable for one end of the balloon-expandable stent region to have a square edge **110**. (See Fig.1). Often an endzone having a square edge may be added to the balloon-expandable region. In some cases, it may be desirable to add a transition region to the balloon-expandable stent region before the square end. Struts or other structural elements may be used to connect the endzone to the rest of the balloon-expandable region.

The self-expanding region **200** may be manufactured from NiTi, SST spring steel, polymers, shape memory material, or other suitable stent material and when released from a restraining apparatus assumes a pre-determined shape and size. When expanded, the self-expanding region **200** preferably has a generally flared or generally conical shape and may take many forms including, but not limited to, those shown in Figures 2a-2f. The self expanding region **200** may be comprised of a web-mesh pattern taking many forms, including, but not limited to, those shown in Figures 3a-3j. In some embodiments, compound angle geometry with hooks at the flared self expanding section may be used to improve contact with vasculature and remodeling of ostial branches. (See also, for example, Figs. 4a and 4b).

As is shown in Figure 1, the self-expanding region **200** is coupled to the balloon-expandable stent region **100** with an encapsulating membrane **300**. In some embodiments, the membrane **300** partially or completely covers both the self expanding region **200** and the balloon expanding region **100**. The membrane **300** is preferably manufactured from balloon-expandable or plastically deformable material, such as PTFE, flouropolymer. PolyVinal Alchol (PVA) cross linked hydrogel, or other suitable material. In an embodiment of the present invention, the material comprising the membrane is shear. In some embodiments, a segment of, or the entirety of, the encapsulating membrane **300** is pre-deployed into the self-expanding segment shape prior to assembly. The membrane is also used to uniformly remodel athrosclerotic plaques and keep this material from protruding through the stent struts and end region struts and filaments.

The endoprosthesis of the present invention may also act as a drug delivery system. In one embodiment of the present invention, an erodable matrix may be used to act as a platform for drug delivery. The erodable matrix may be composed of an erodable polymer system that is biocompatible. Among the numerous useful drugs that may be delivered by the graft platform described herein, are anti-restenosis drugs.

The present invention also provides a delivery system for intraluminal ostial endoprosthetic devices. The delivery system may comprise an over-the-wire delivery apparatus or a rapid exhange shuttle system. If an over-the-wire system is used, the delivery apparatus may traverses over a guide wire **500** (e.g., a 0.010 to 0.038 inch wire) to a site for deployment.

(See e.g. Figure 5). As is shown in Figure 6, marker bands **510, 512, 514** on the delivery apparatus indicate the deployment location of a segment of the device in a vasculature. The end result being that the endoprosthesis is delivered to a lesion site.

In one embodiment, as is shown in Figures 5- 12, the delivery system of the present invention employs a pull-back sheath **520**, which is a tubular segment of a pull-back or restraining system that retains the self-expanding segment **200** from premature deployment. This also allows for precise deployment of the entire device at an ostium. A ring or other suitable restraining apparatus may be used instead of or in addition to the sheath **520.**

The balloon-expandable stent region **100** of an intraluminal ostial endoprosthesis is mounted on a balloon delivery device **530**. As is shown in Figure 6, as the balloon begins to inflate and the balloon-expandable segment begins to deploy. As the balloon **530** inflates, the self-expanding region **200** begins to pull out of the pull-back sheath **520**. As is shown in Figure 7, by the time the balloon expanding stent region **100** is fully deployed, the self-expanding region **200** exits the pull-back sheath **520**. The self-expanding region **200** begins elastic deformation to a predetermined size. (See Figure 8-11). The balloon is then deflated (see Figure 12) and the delivery apparatus is removed. The result is that the intraluminal endoprosthesis is anchored into the ostium as shown in Figures 13 - 18.

While in the embodiment described above, the self-expanding region may automatically exit a restraining apparatus after the balloon-expandable stent portion is expanded to a certain point, it may be desirable for the self-expanding segment to remain restrained in a sheath, ring, or other suitable restraining means until the implanting medical professional desires to allow it to self expand. Thus, in some embodiments, an affirmative action, such as removing the restraining means, must be taken before the self-expanding portion self expands.

The present invention allows for location of the delivery apparatus and the intraluminal endoprosthesis to be obtained and relocated if necessary, even after partial inflation of the balloon-expandable portion of the stent **100.**

Figures 19-118 clearly depict additional details or provide a different perspective of exemplary embodiments of the present invention and are included herein for illustrative purposes and are not in any way intended to limit the scope of the present invention.

What is claimed is:

1. An intraluminal endoprosthesis comprising:

a self-expanding section, the self-expandable section, when expanded, having a flared shape;

a balloon-expandable stent section; and

a membrane at least partially covering the self-expanding section and the balloon-expandable stent section and connecting the balloon-expandable stent to the self-expanding section

2. The endoprosthesis of claim 1, wherein the membrane acts as a drug delivery platform.

3. The endoprosthesis of claim 1, wherein exposed sections thereof act as a delivery platform for theraputic agents.

4. The endoprosthesis of claim 1, wherein the membrane is a flouropolymer.

5. The endoprosthesis of claim 1, wherein the membrane is erodable.

6. The endoprosthesis of claim 1, wherien the membrane is manufactured from PTFE.

7. The endoprosthesis of claims 1, 2, 3, 4, 5, or 6 wherein, when it is deployed, the self-expanding section has an outer edge with a radius greater than the expanded radius of the balloon-expandable stent section.

8. The endoprosthesis of claim 1, wherein the self-expandable section is manufactured from NiTi.

9. The endoprosthesis of claim 1, wherein the self-expanding section is manufactured from spring stainless steel.

10. The endoprosthesis of claim 1, further comprising hooks on an outer end of the self-expanding section.

11. The endoprosthesis of claim 10, wherein the balloon-expandable section comprises a plurality of helical segments.

12. An apparatus for delivering to an intralumen site an endoprosthesis having a self-expanding region and a balloon-expandable section, the apparatus comprising:

a distal region;

a balloon delivery device that encapsulates at least a portion of distal region and on which the balloon-expandable stent section is crimped;

a pull-back sheath for encapsulating at least a portion of the self-expanding region, the pull-back sheath surrounding part of the distal region of the apparatus;

one or more marker bands located on the distal region for locating the position of the balloon-expanding section when the endoprosthesis is in a lumen of a vessel.

13. The apparatus of claim 12, wherein one marker band is distinguishable from another when the delivery device is in a lumen of a vessel.

14. The apparatus of claim 12 or 13, further comprising a guidewire and wherein the distal region traverses the guidewire en route to the site.

15. The apparatus of claim 12 or 13, further comprising a rapid exchange shuttle, wherein the the distal region traverses the rapid exchange shuttle en route to the site.

16. The apparatus of claim 12 or 13, wherein the number of marker bands is three.

17. A method for deploying a flared intraluminal ostial endoprosthetic device, the method comprising the steps of:

mounting a balloon-expandable portion on a balloon delivery device;

encapsulating at least a portion of a self-expanding portion in a sheath;

inserting the endoprosthesis in a region of a lumen near an ostial legion;

radiologically determining the location of a distal region of the delivery device on which the endoprosthesis is mounted;

partially inflating the balloon delivery device;

radiologically verifing that the endoprosthesis is in a proper location;

after determining that the endoprosthesis is not in the proper location, moving the endoprosthesis to the proper location;

inflating the balloon device further;

causing the sheath to be removed from the self-expanding region;

removing the sheath and the balloon delivery device from the lumen.

18. A method for delivering an ostial endoprosthesis having a balloon-expandable portion and a self-expanding portion, the method comprising:

transporting the endoprosthesist to an intralumen site for deployment on a delivery device;

verifying the location of the delivery device;

partially expanding a portion of the endoprosthesis;

verifying that the endoprosthesis is in a desired location at the site via radiopaque marker bands on a delivery apparatus;

repositioning the endoprosthesis, if it is not in a desired location; and

expanding the remainder of the endoprosthesis.

19. The method of claim 18, wherein the step of partially expanding a portion of the endoprosthesis comprises inflating a balloon apparatus.

20. The method of claim 19, wherein the step of expanding the remainder of the endoprosthesis comprises, balloon inflating the portion of the endoprosthesis and causing a restraining assembly to be removed from a self-expanding portion of the endoprosthesis, thereby allowing the self-expanding portion to expand.

21. An intraluminal endoprosthetic device comprising:

a first self-expanding end, the self expanding end forming a generally cone shaped structure when the endoprosthesis is deployed;

a second end having a square edge;

a tubular balloon-expandable stent body disposed between the second end and the first self-expanding end; and

an encapsulating material connecting the first self-expanding end to the balloon-expandable stent body.

22. The endoprosthesis of claim 21, further comprising a transition region between the stent body and the square end.

23. The endoprosthesis of claim 21, wherein the first self-expanding region has a flared portion.

24. The endoprosthesis of claim 23, wherein the flared portion is comprised of hooks.

25. The endoprosthesis of claim 24, wherein the hooks form compound angles.

26. The endoprosthesis of claim 21, wherein the encapsulated portion of the self expanding region is formed prior to mounting the endoprosthesis in a delivery catheter.

27. A method for deploying an intraluminal endoprosthesis having a self-expanding portion and a balloon-expandable portion, the method comprising:

delivering the endoprosthesis to a site via a delivery apparatus;

at least partially expanding a balloon-expandable portion of the endoprosthesis;

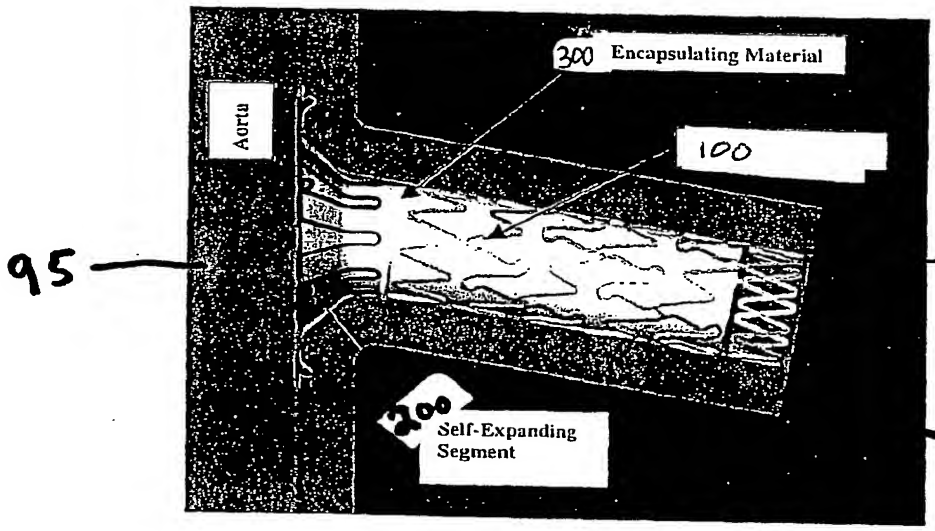
radiologically verifying that the delivery apparatus is in a proper location; and

removing a restraining means from a self-expanding portion of the endoprostheis.

28. The method of claim 27, further comprising inflating further the balloon-expandable portion.

29. The method of claims 27 or 28, wherein the delivery apparatus travels over a guide wire en route to the site.

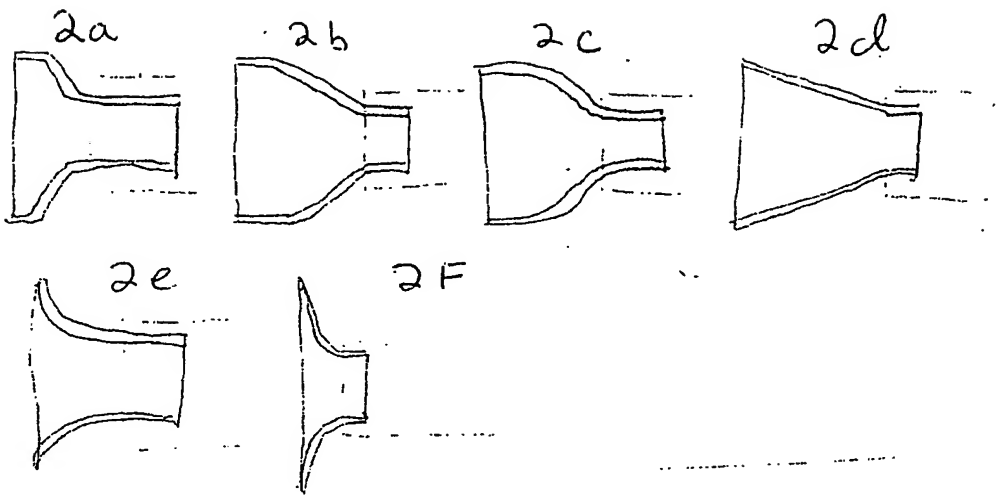
30. The method of claims 27 or 28, wherein the delivery apparatus comprises a rapid exchange shuttle.



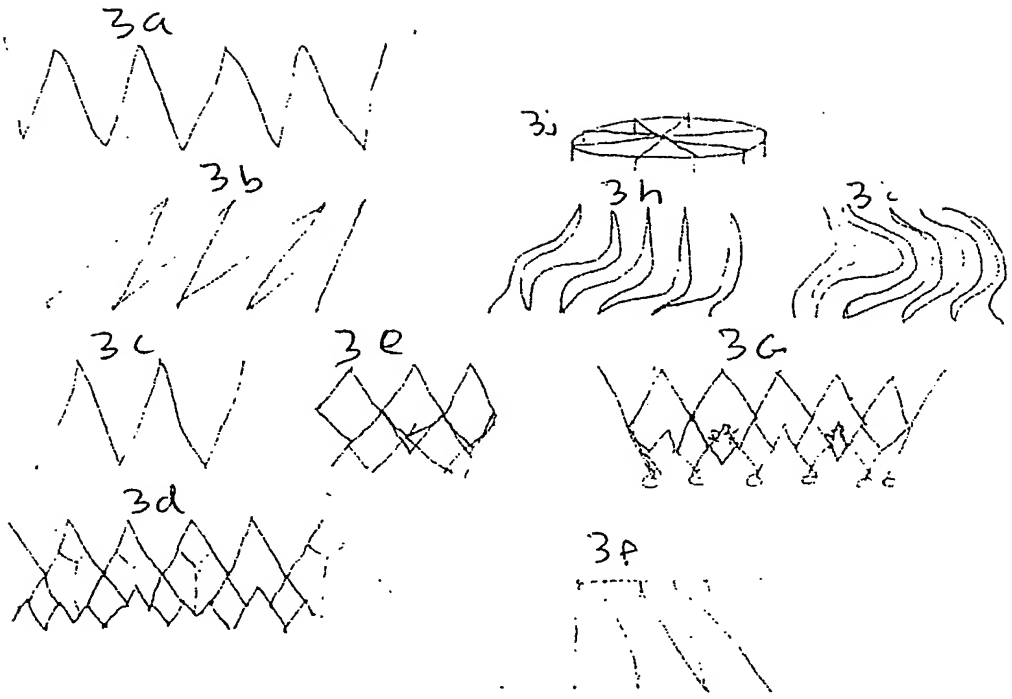

*Orbus Flared Ostial Stent (renal artery indication)*

Fig. 1

Figs 2a-2F



Figs. 3a - 3j



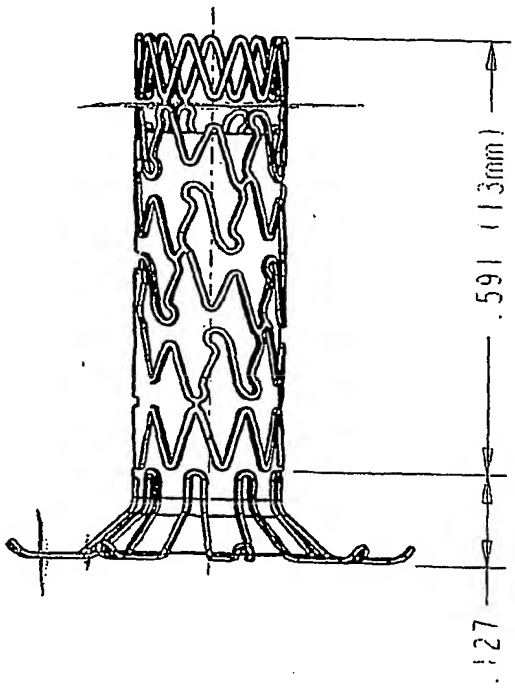
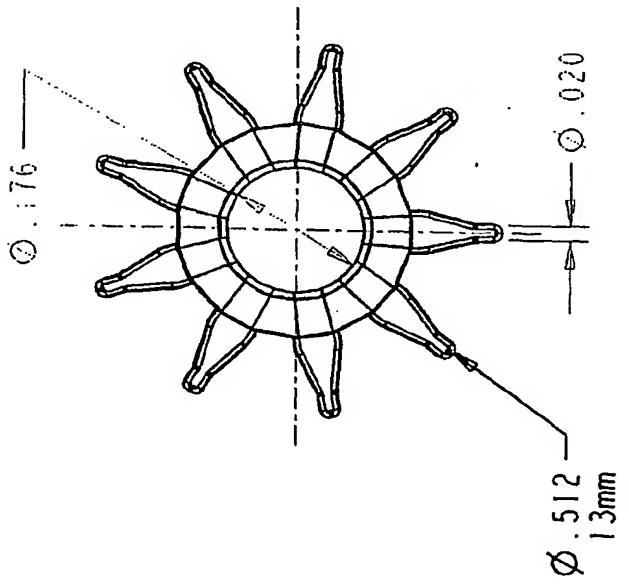



Fig 4b




SCALE 5.000

Fig 4a

Orbus -Ostial Stent Illustration

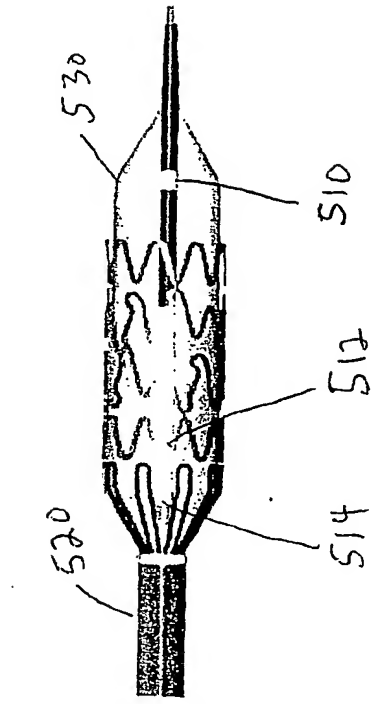



Fig 6 Flared Ostial Stent Deployment

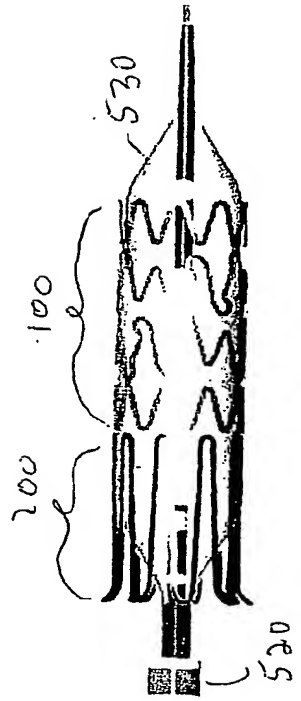



Fig 8 Flared Ostial Stent Deployment

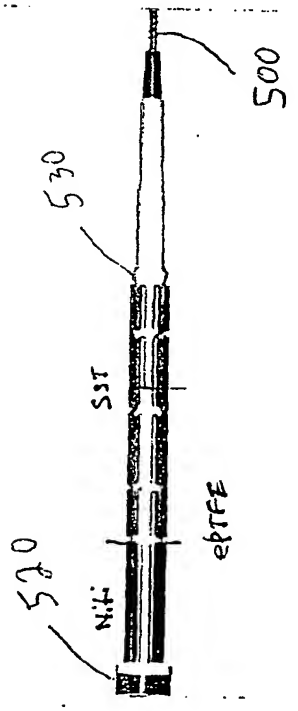



Fig 5 Flared Ostial Stent Deployment

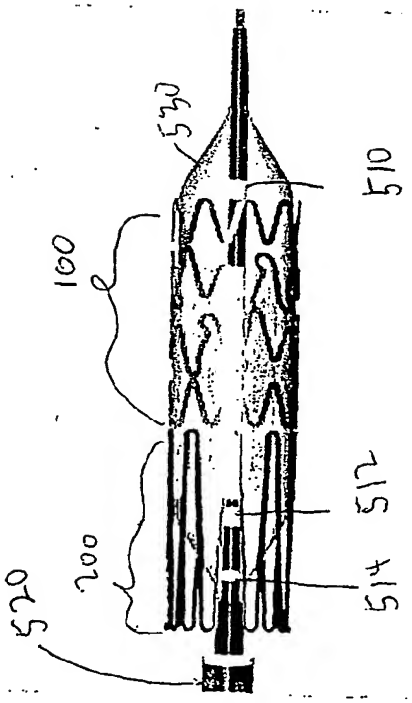
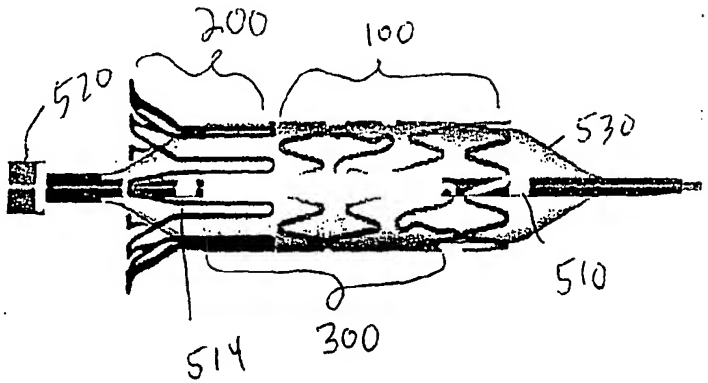
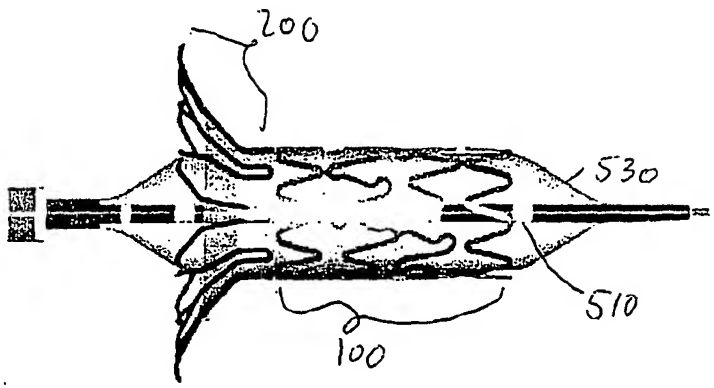



Fig 7 Flared Ostial Stent Deployment

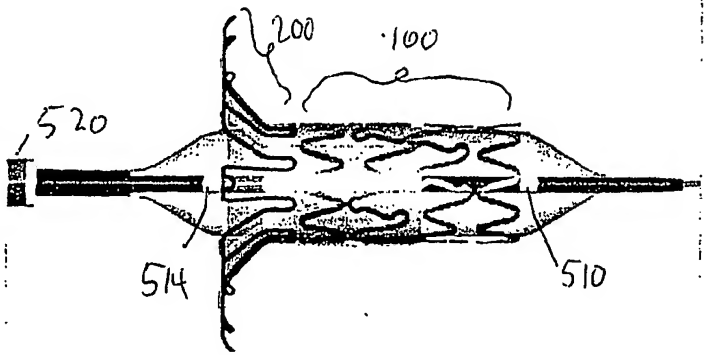
# Orbus -Ostial Stent Illustration




Flared Ostial Stent Deployment Fig 9




Flared Ostial Stent Deployment Fig 10




Flared Ostial Stent Deployment Fig 11

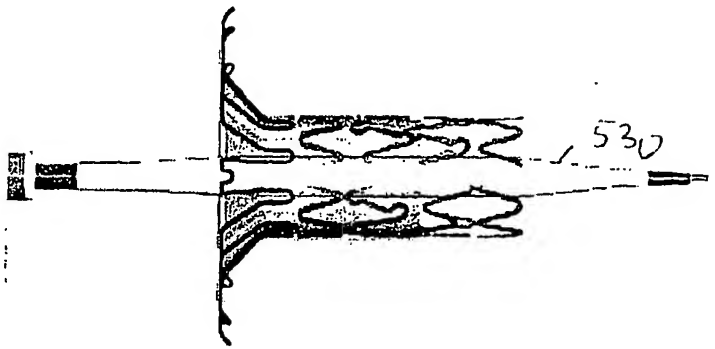



Fig 12

Flared Ostial Stent Deployment

Orbus -Ostial Stent Illustration

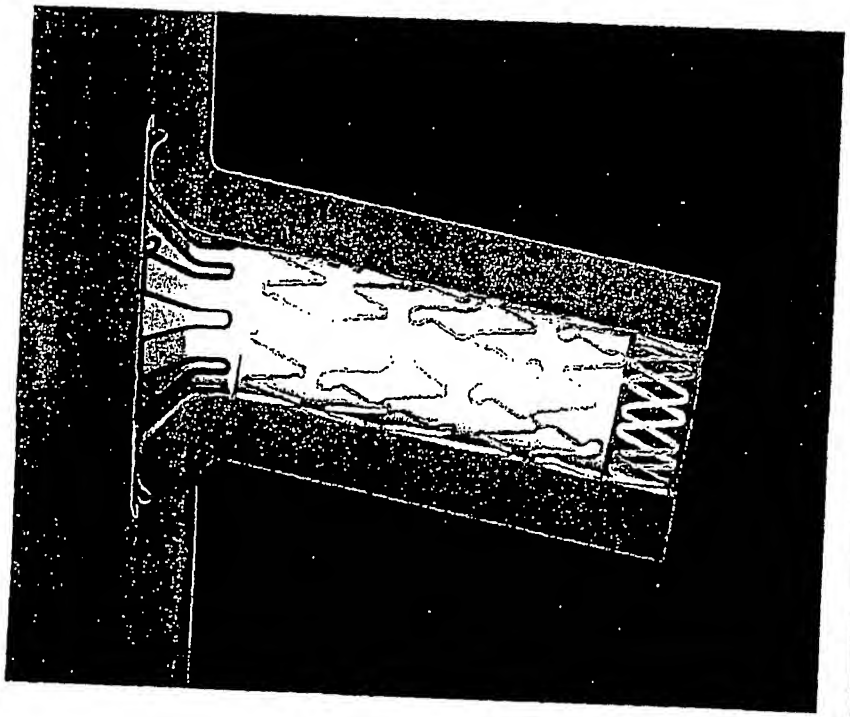


Fig 13

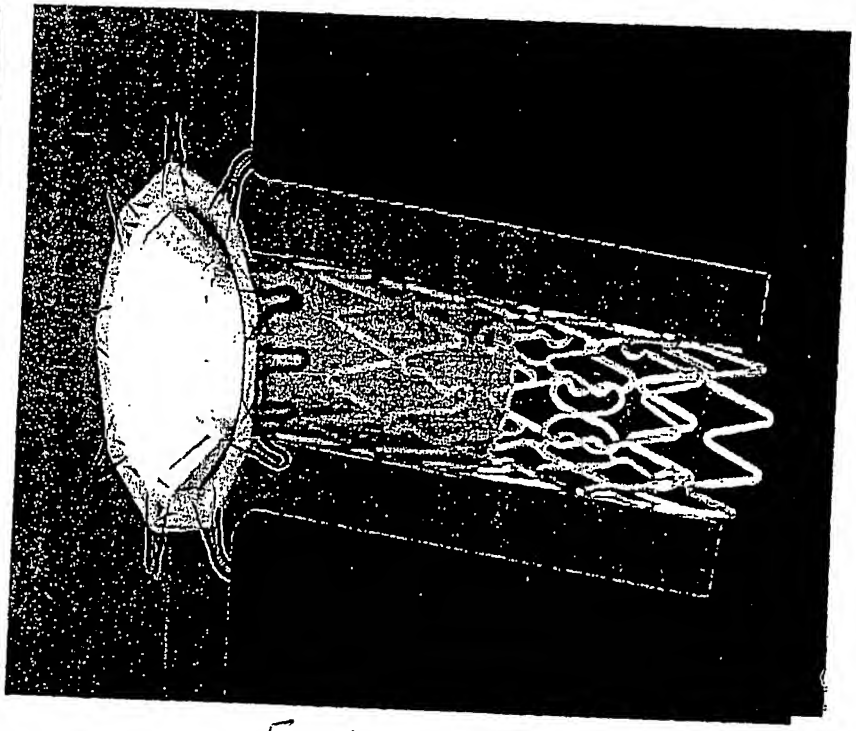


Fig 14

Flared Ostial Stent Deployment 09

Flared Ostial Stent Deployment 10

Fig 16

trumpet_stent_planar3A



Fig 18

trumpet_stent_planar5



Fig 15

trumpet_stent_planar3



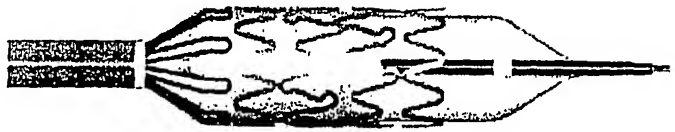
Fig 17

trumpet_stent_planar4

Fig 19

Flared Ostial Stent Deployment 01

Fig 20

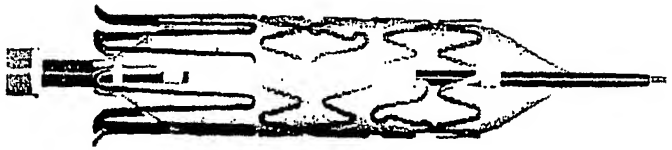


Flared Ostial Stent Deployment 02

Fig 21

Flared Ostial Stent Deployment 03

Fig 22



Flared Ostial Stent Deployment 04

Fig 23

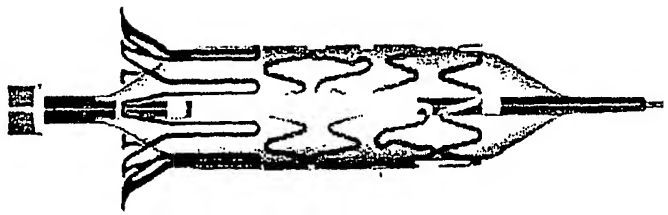
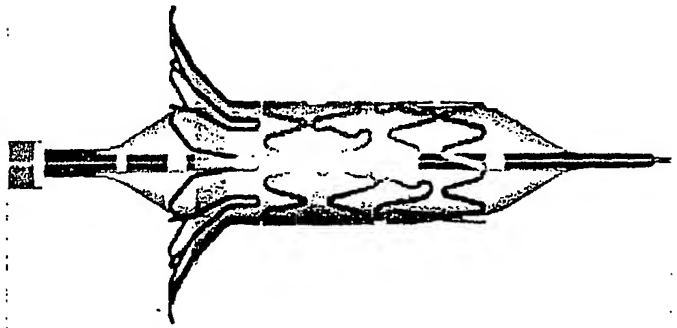


Fig 24



Flared Ostial Stent Deployment 05 Flared Ostial Stent Deployment 06

Fig 25

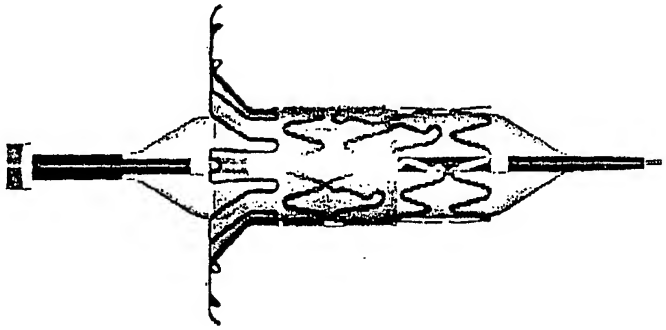
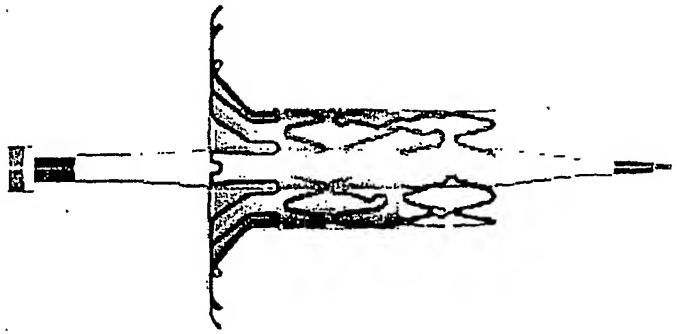


Fig 26

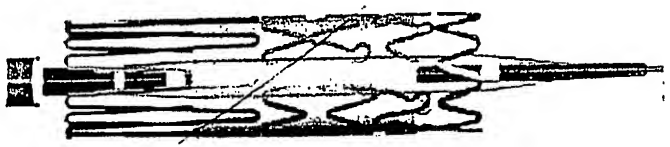


Flared Ostial Stent Deployment 07 Flared Ostial Stent Deployment 08



WO 03/063729 PCT/US03/02409

Fig 27



mains1d

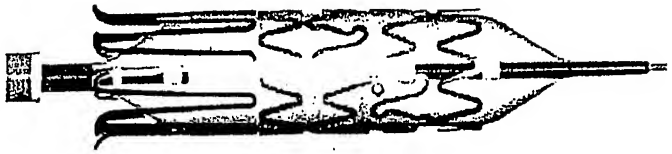
Fig 28

mains1i

Fig 29

mains2d

Fig 30



mains2i

Orbus -Ostial Stent Illustration



Fig 32



Fig 31

mains3i



Fig 34

mains4i



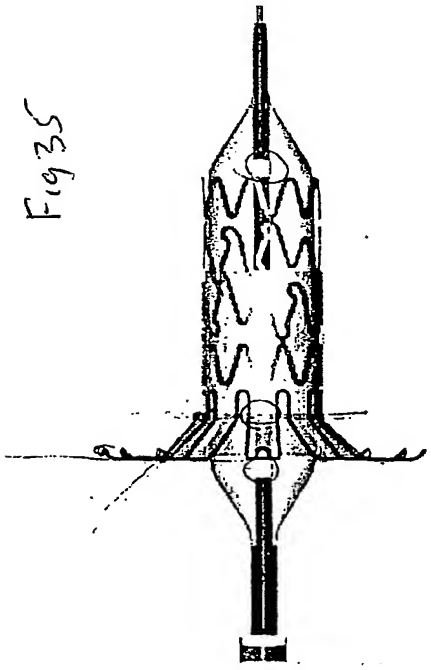
mains3d

Fig 33

mains4d (Deployed)

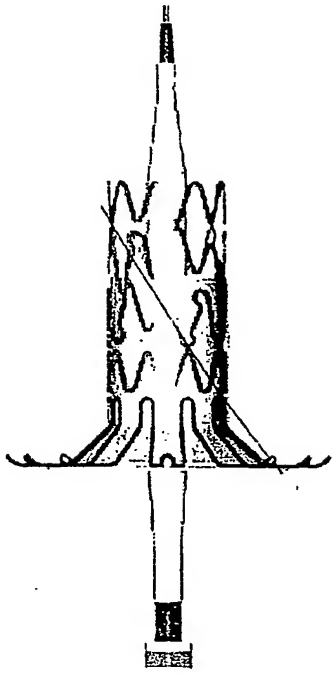
Orbus -Ostial Stent Illustration

Fig 35



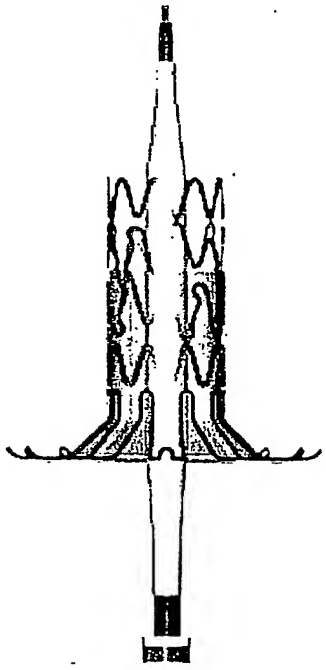
inflated_deployed8

Fig 36



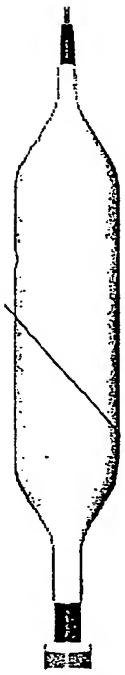
inflated_deployed9

Fig 37



inflated_deployed10

Fig 38



inflated_deployed11

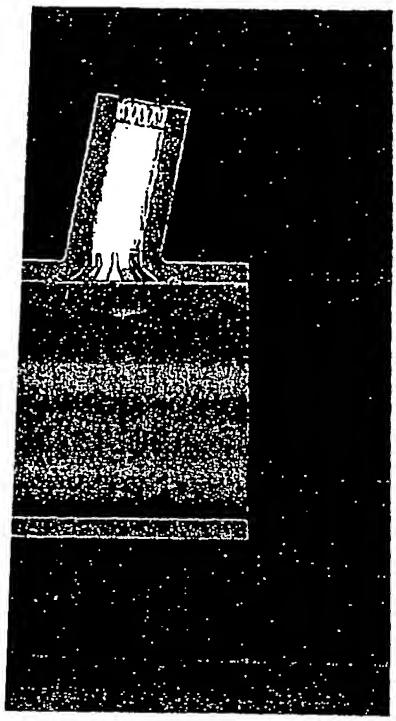


Fig 40

trumpet_stent_planar2

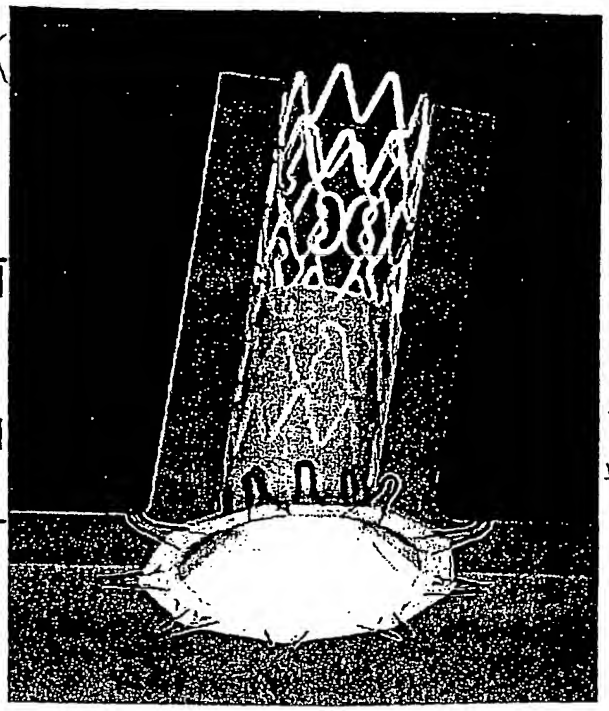


Fig 42

trumpet_stent_planar2b

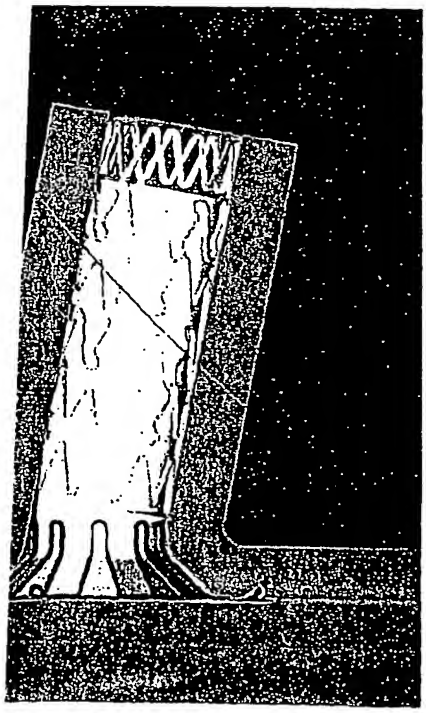


Fig 39

trumpet_stent_planar

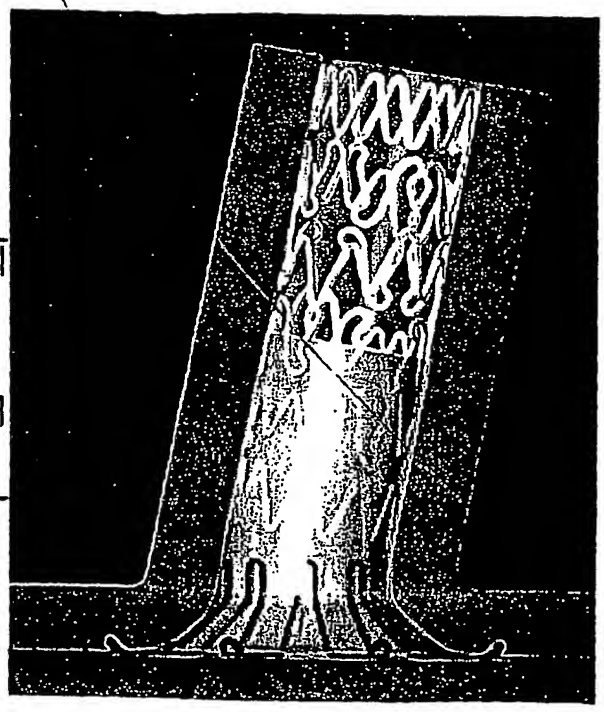


Fig 41

trumpet_stent_planar2a

Orbus -Ostial Stent Illustration

Fig 44



deflated_sheathed4

Fig 46



deflated_sheathed22

Fig 43



deflated_sheathed3

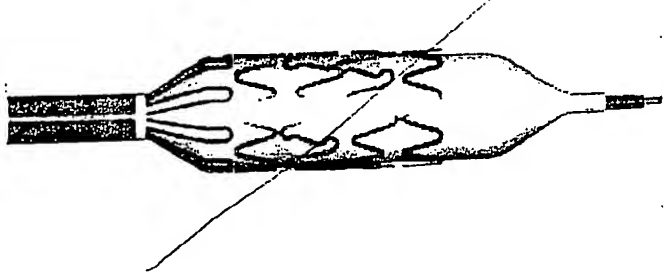
Fig 45



deflated_sheathed20

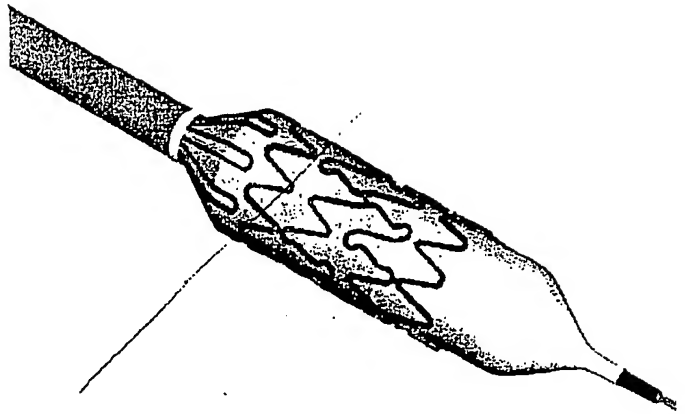
Orbus -Ostial Stent Illustration

Fig 47



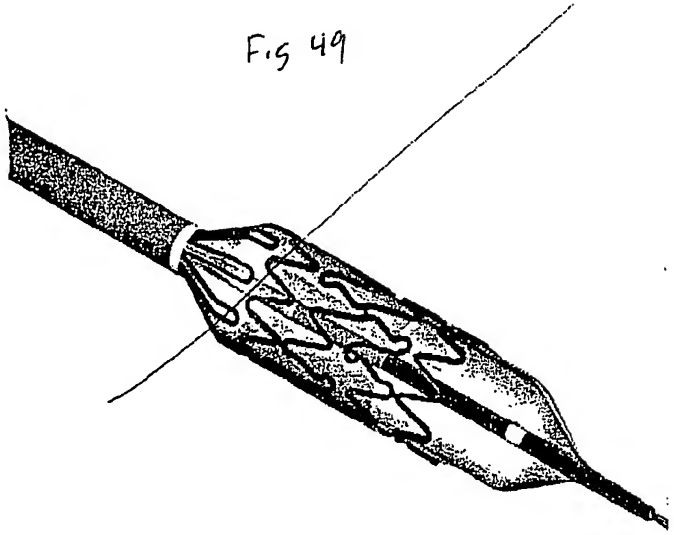
inflated_deployed12

Fig 48



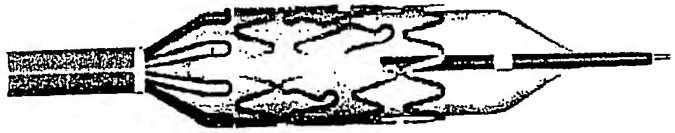
inflated deployed13

Fig 49



inflated_deployed14

Fig 50



Flared Ostal Stent Depl. 3

inflated_deployed15

Orbus -Ostial Renal Illustration



Fig 51

niti_rob_5a



Fig 52

niti_rob_5b



Fig 53

niti_rob_5c



Fig 54

niti_rob_5d

Orbus -Ostial Stent Illustration

Fig 56



main2i

Fig 58



main3i

Fig 55



main2d

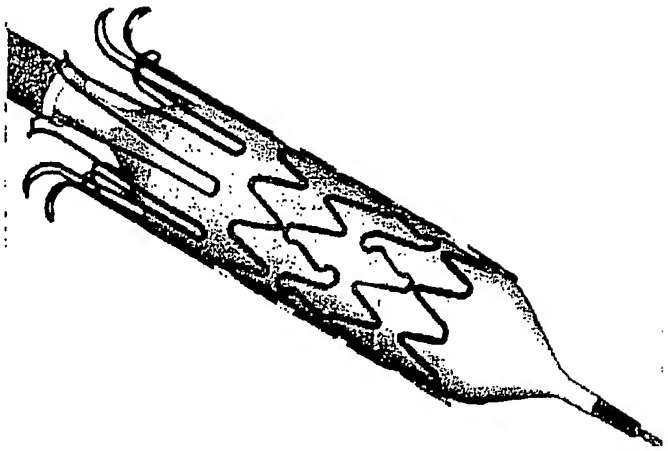
Fig 57



main3d

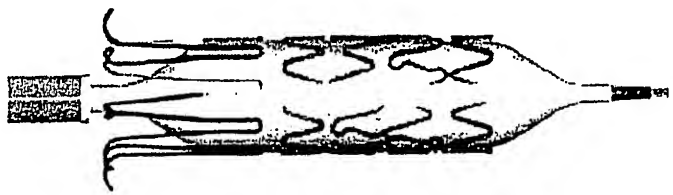
Page

Fig 59



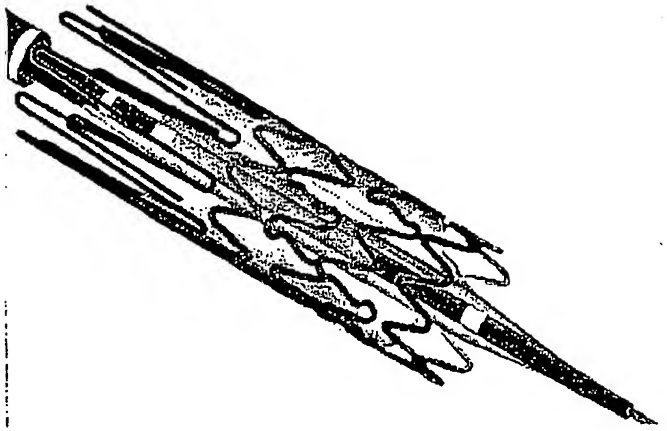
inflated_deployed56

Fig 60



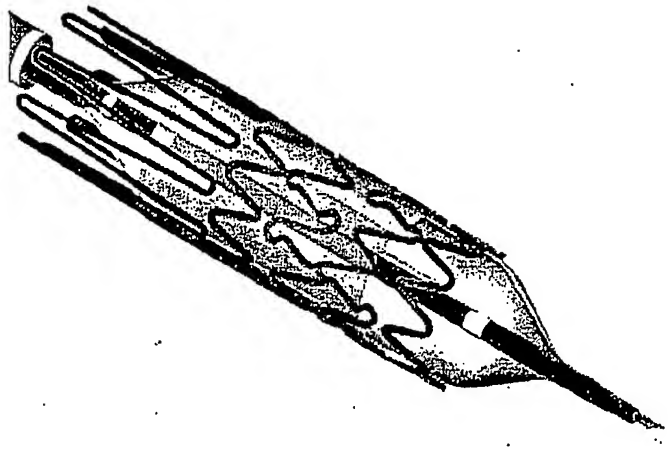
inflated_deployed57

Fig 61



main1d

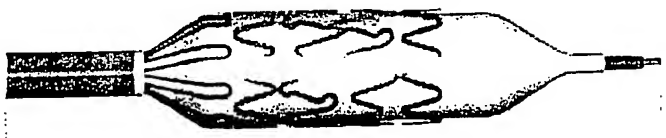
Fig 62



main1i

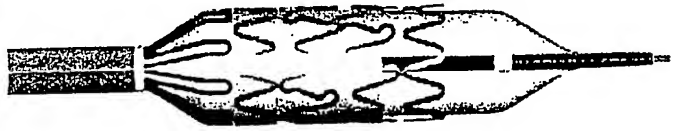
Orbus -Ostial Stent Illustration

Fig 63



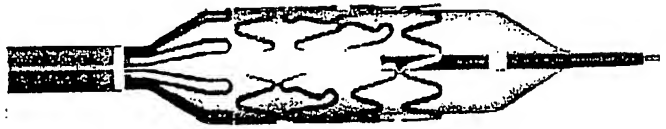
inflated_deployed30

Fig 64



inflated_deployed31

Fig 65



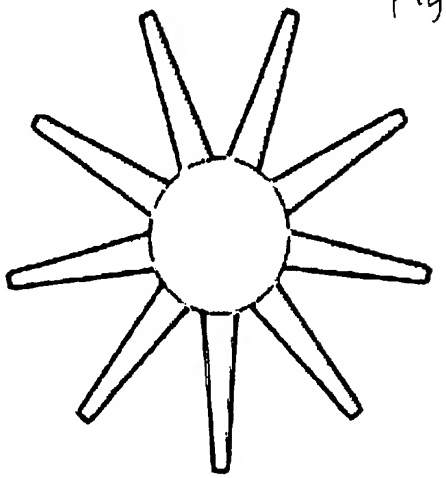
inflated_deployed32

Fig 66

inflated_deployed33

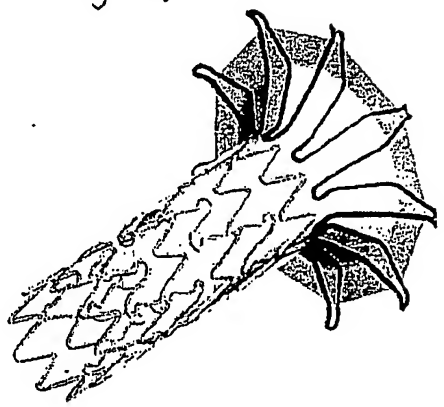
Orbus -Ostial Renal A Illustration

Fig 67



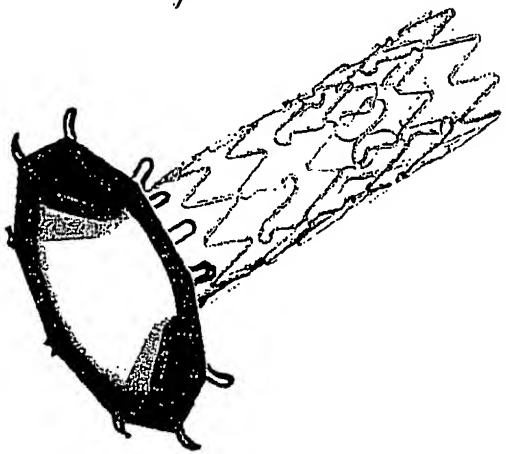
trumpet_14x2mm

Fig 68



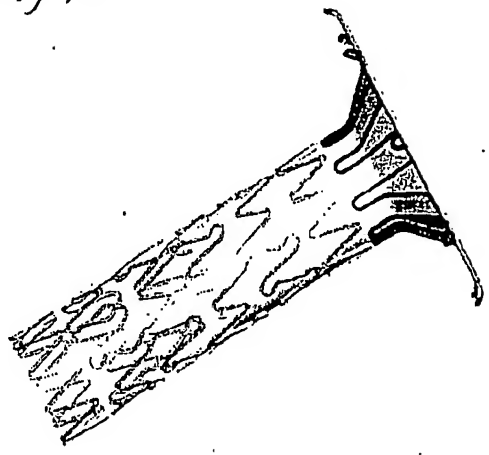
trumpet_14x2mm3

Fig 69



trumpet_14x2mm4

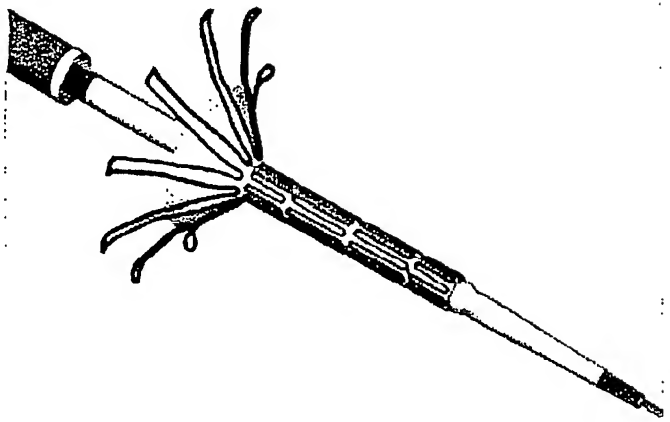
Fig 70



trumpet_14x2mm6

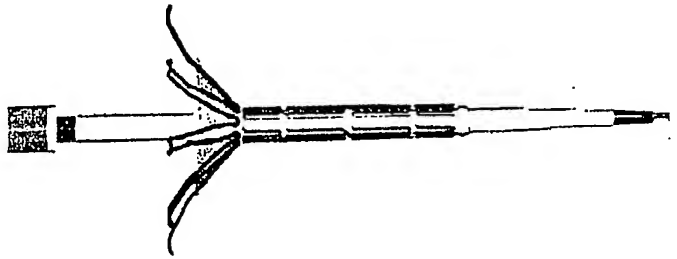
Orbus -Ostial Stent Illustration

Fig 71



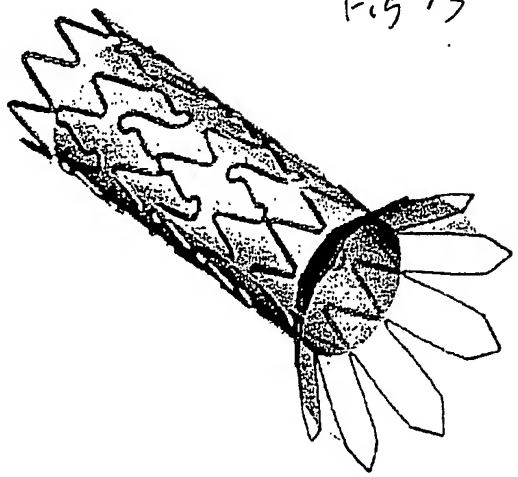
blune_deflated_trifold3

Fig 72



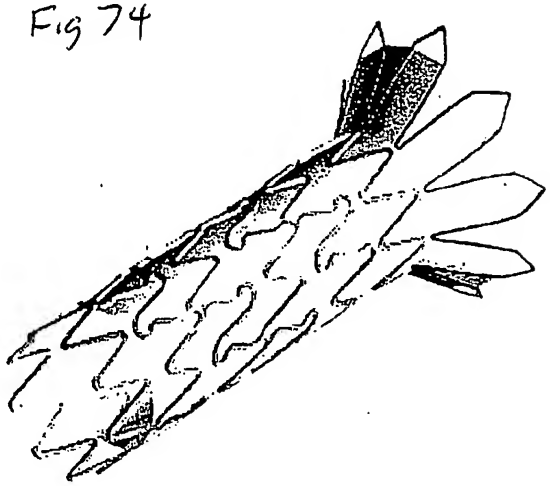
blune_deflated_trifold4

Fig 73



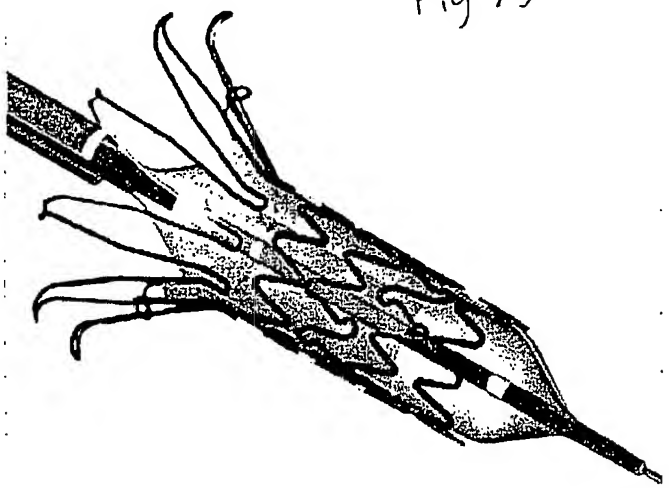
cone-2_6-9mm

Fig 74



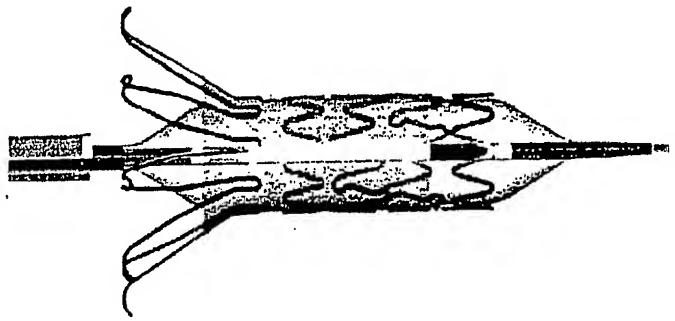
cone-2_6-9mmb

Fig 75



inflated_deployed52

Fig 76

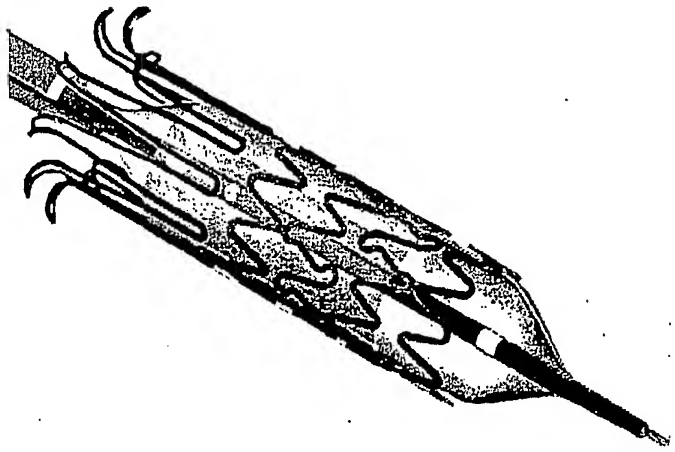


inflated_deployed53

Fig 77

inflated_deployed54

Fig 78



inflated_deployed55

Orbus -Ostial Stent Illustration

Fig 80



main4i

Fig 82



main5i

Fig 79



main4d

Fig 81



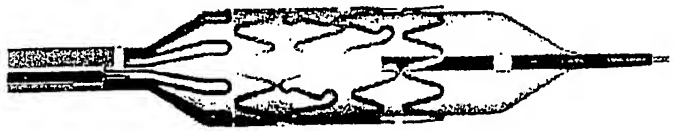
main5d

Orbus -Ostial Stent Illustration

Fig 83

inflated_deployed34

Fig 84

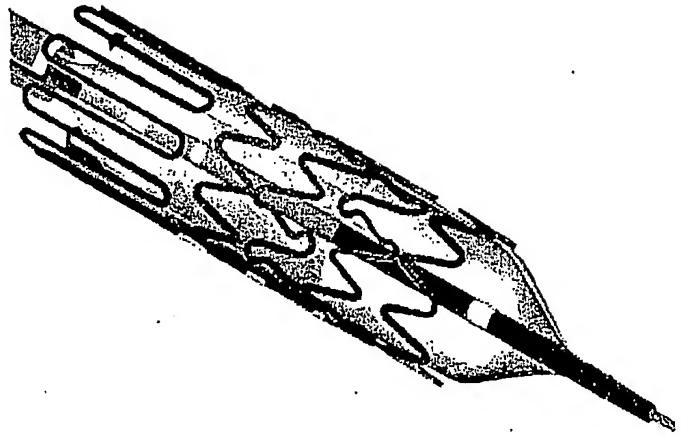


inflated_deployed35

Fig 85

inflated_deployed40

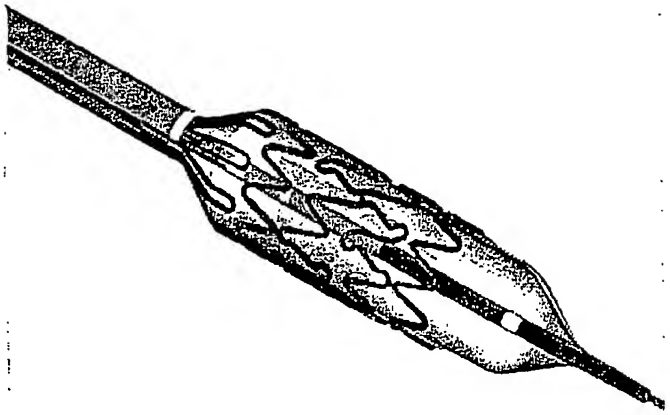
Fig 86



inflated_deployed41

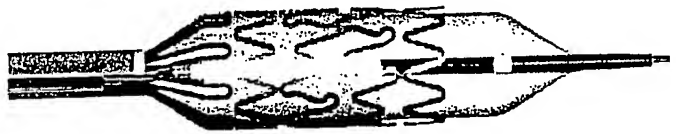
Orbus -Ostial Stent Illustration

Fig 87



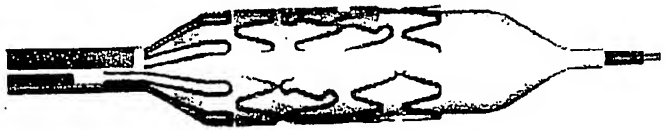
inflated_deployed16

Fig 88



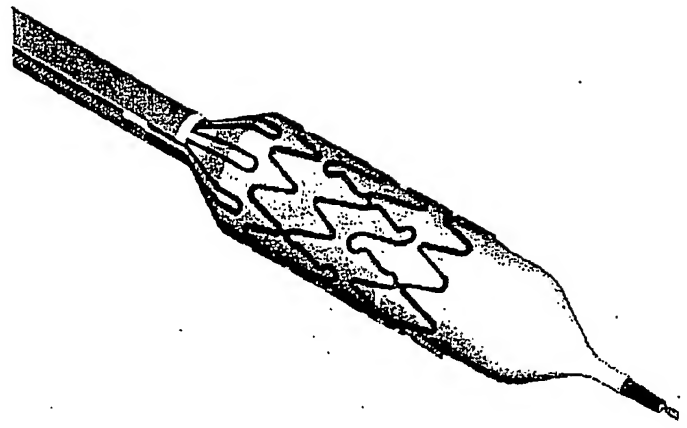
inflated_deployed17

Fig 89



inflated_deployed18

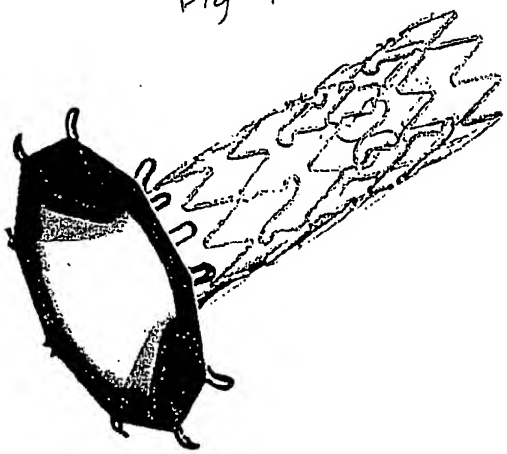
Fig 90



inflated_deployed19

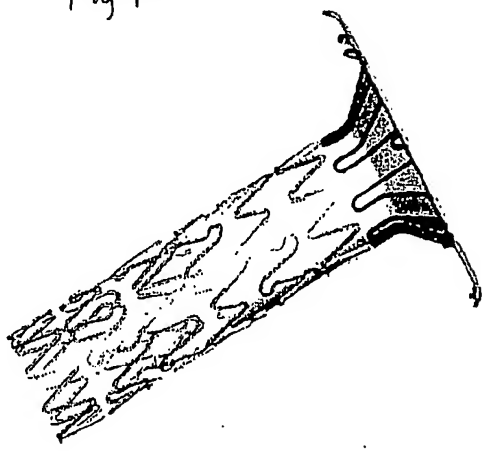
Orbus -Ostial Stent Illustration

Fig 91

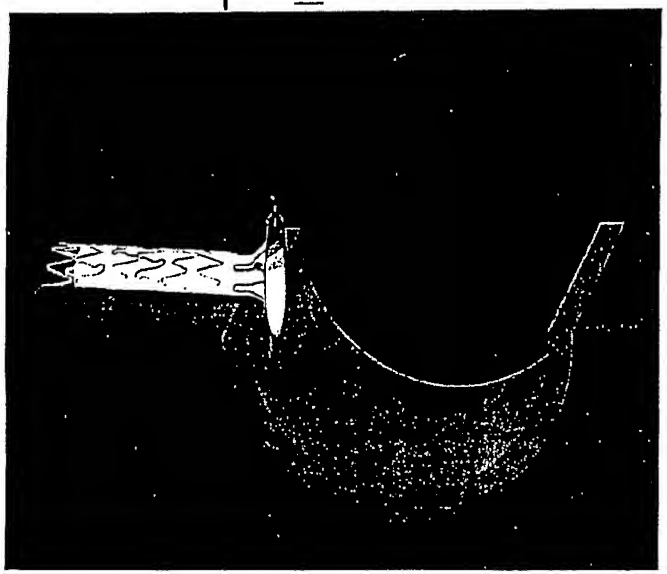


trumpet_14x2mm4

Fig 92



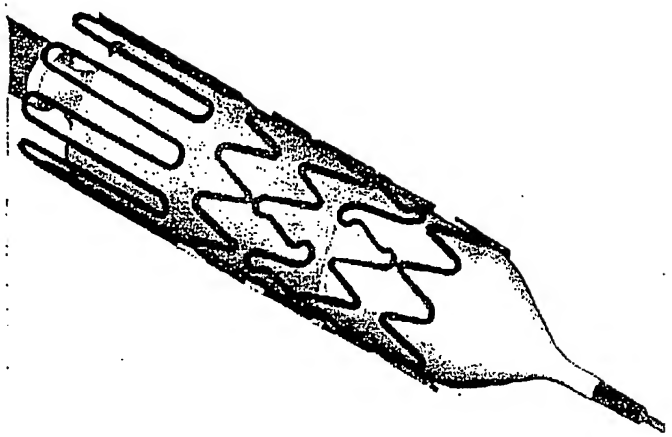
trumpet_14x2mm6



trumpet_stent_planar5

Orbus -Ostial Stent Illustration

Fig 94

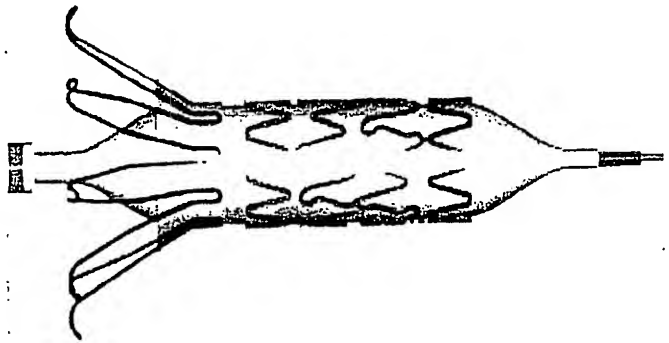


inflated_deployed42

Fig 95

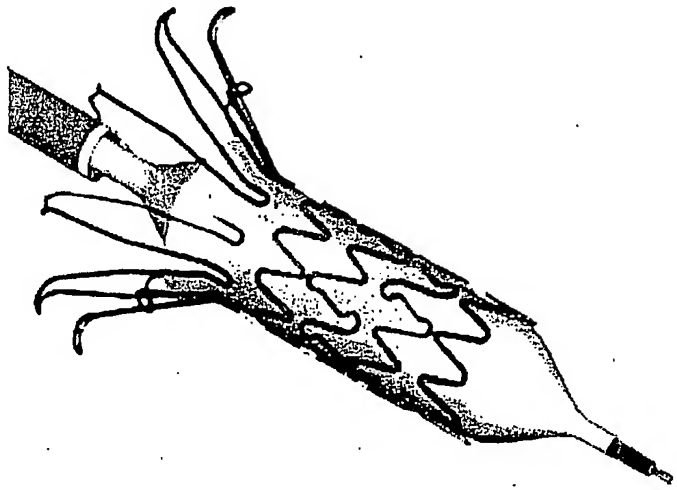
inflated_deployed43

Fig 96



inflated_deployed50

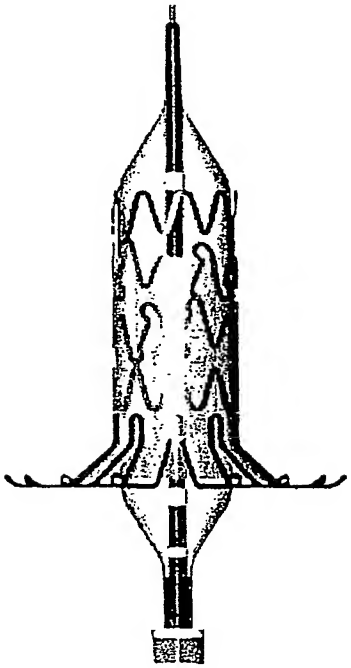
Fig 97



inflated_deployed51

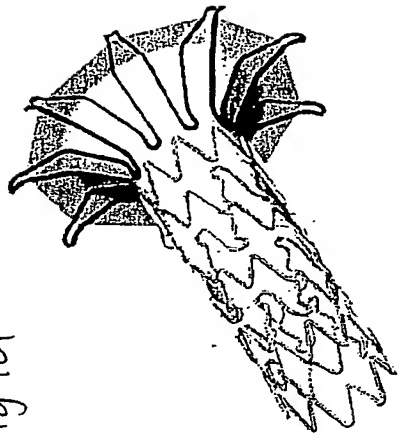
Orbus -Ostial Stent Illustration

Fig 99



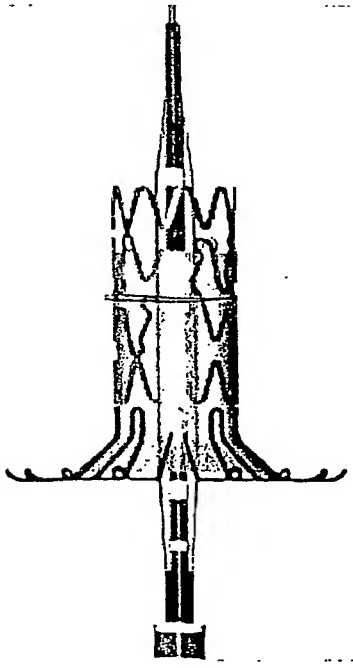
mains5i

Fig 101



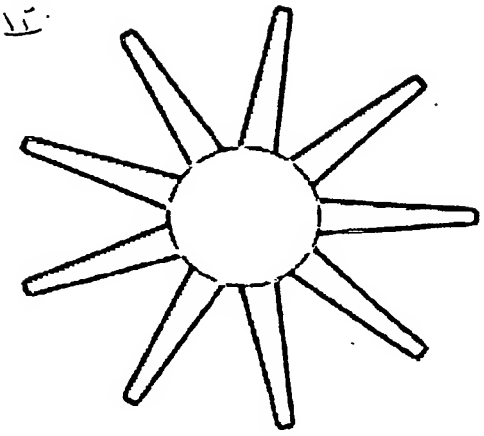
trumpet_14x2mm3

Fig 98



mains5d

Fig 100



trumpet_14x2mm

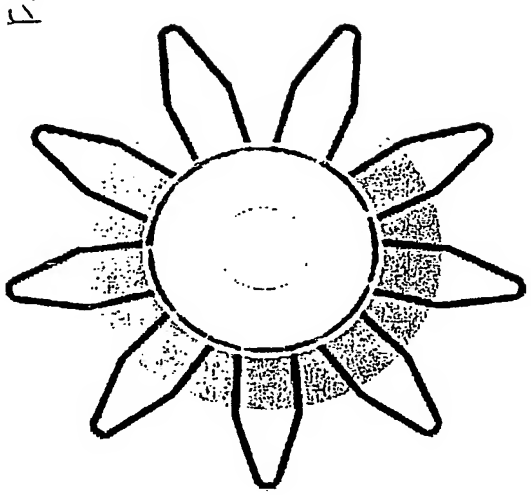
Orbus -Ostial Stent Illustration




Pane

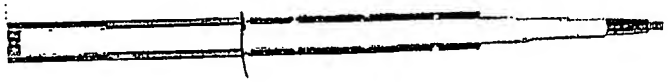
Orbus -Ostial Renal 5/01 Illustration

Fig 10b



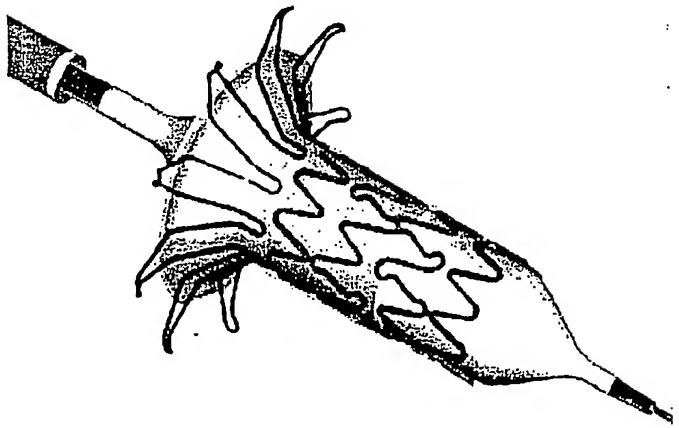
niti_rob_5e

Fig 107



deflated_sheathed23

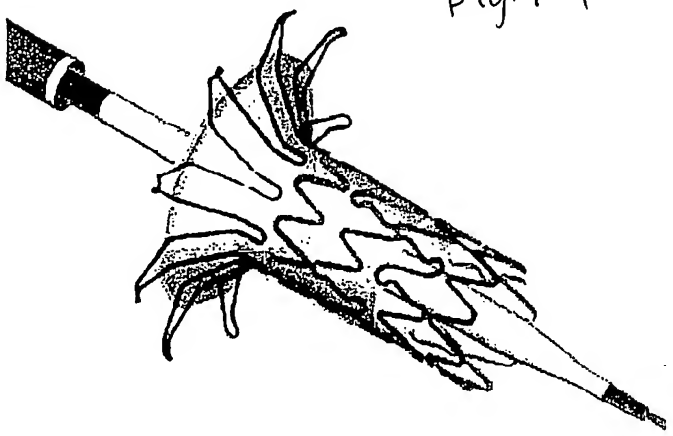
Fig 108



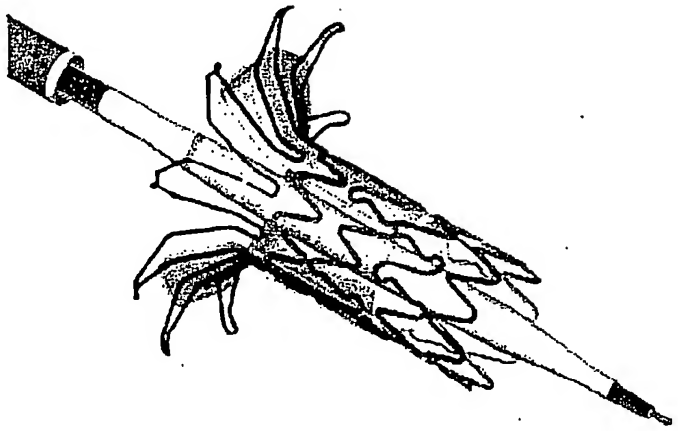
inflated_deployed

Fig 110 (4)

Fig 109



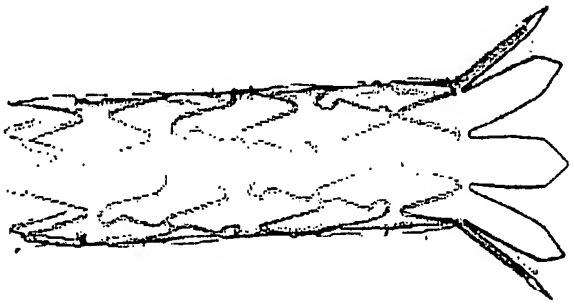
inflated_deployed2



inflated_deployed3

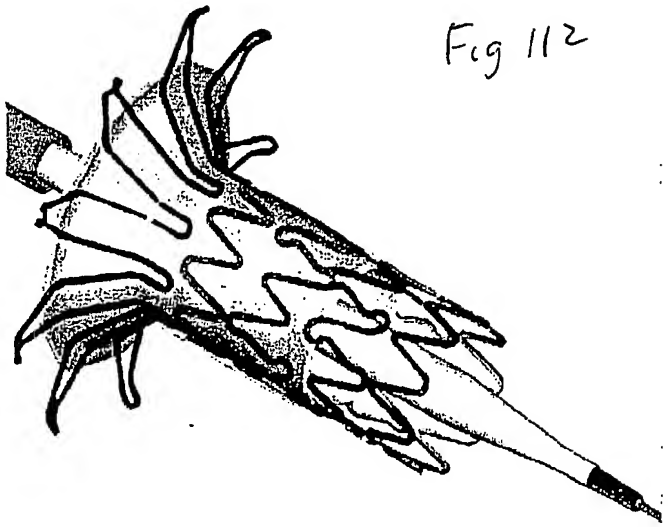
Orbus -Ostial Stent Illustration

Fig 111



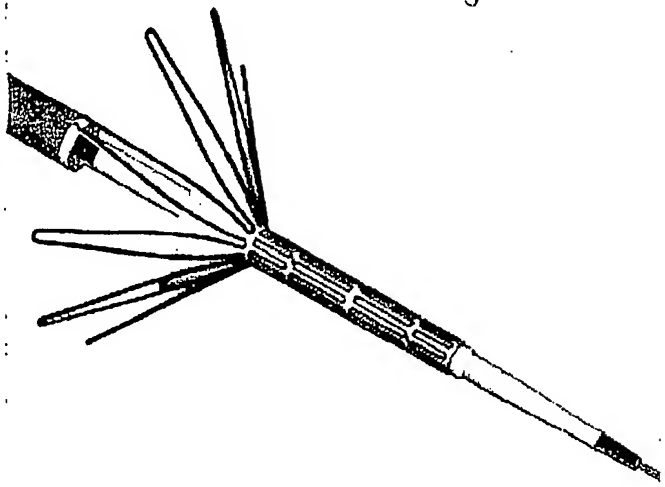
cone-2_6-9mmc

Fig 112



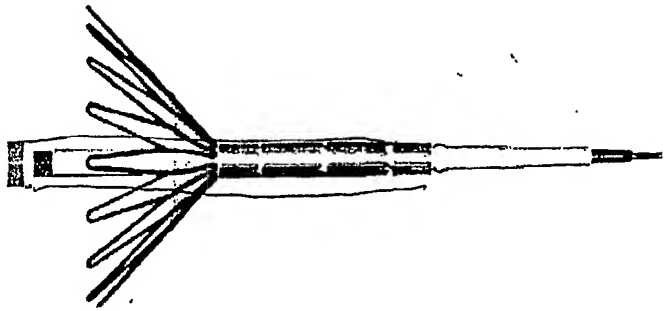
deflated_deployed

Fig 113



deflated_sheathed

Fig 114



deflated_sheathed

Orbus -Ostial Stent Illustration

Fig 16



Fig 15



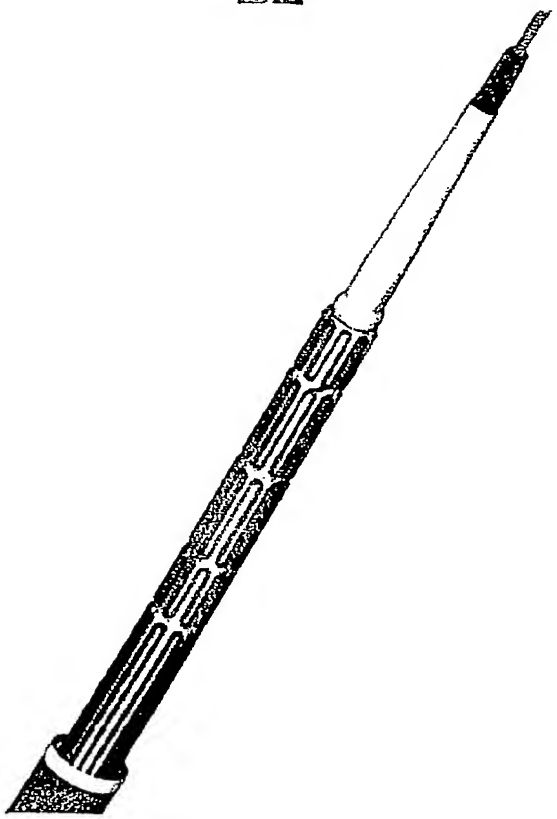
blune_deflated_trifold50 blune_deflated_trifold51

Orbus -Ostial Stent Illustration

Fig 116

blune_deflated_trifold53

Fig 117



blune_deflated_trifold52

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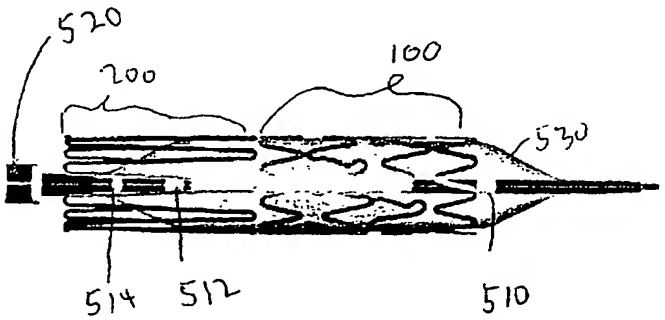
(54) Title: FLARED OSTIAL ENDOPROSTHESIS AND DELIVERY SYSTEM




Flared Ostial Stent Deployment

(57) Abstract: An intraluminal endoprosthesis having a conically shaped first end and a tubular shaped balloon-expandable stent (100) for a main body is disclosed. The conically shaped first end may form a flare to the main body and is particularly well suited for in ostium use. The first end is preferably self-expanding and the main body is preferably balloon-expandable (100). Also disclosed is a delivery device for delivering intraluminal ostial endoprosthetic devices, especially those disclosed herein, to a site for deployment. The delivery device may comprise an over-the-wire (500) system or may comprise a rapid-exchange shuttle system. The self-expanding portion (200) of the endoprosthesis is encapsulated in a sheath (520) or other restraining apparatus on the delivery device. The balloon-expandable stent (100) portion of the endoprosthesis is crimped onto a balloon delivery device (530). The delivery system and endoprosthesis of the present invention allow the endoprosthesis to be partially expanded and relocated if it is determined that it is not located in the proper location. To aid in positioning, the delivery device may comprise marker bands (510, 512, 514).

WO 03/063729 A3

# INTERNATIONAL SEARCH REPORT

International application No.
PCT/US03/02409

**A. CLASSIFICATION OF SUBJECT MATTER**

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US CL : 623/1.11

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/1.11; 606/108,194,198

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|---|---|---|
| X | US 6,254,609 B1 (Vbra et al.) 03 July 2001 (See Figs. 1, 4-5, 8 and abstract, col. 2, lines 1-60). | Claims 1-16 and 21-26 |
| A | US 5,306,294 A (Winston et al.) 26 April 1994 (See abstract, figs. 2-3). | 17-20 and 27-30 |

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